

HIV and Hepatitis C Counseling, Testing and Referral Site Policies and Procedures

2016

The policies and procedures on the following pages are applicable to all sites receiving reimbursement through the North Dakota Department of Health for HIV and Hepatitis C counseling, screening, testing and vaccination activities. The policies may or may not be applicable to other agencies involved in testing.



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*Current personnel are listed at: www.ndhealth.gov/HIV/CTR/CTR.htm

Questions should be directed as follows:

- Reimbursement & Contracts: HIV.STD.TB.Viral Hepatitis Program Manager
- CTR Program Operations & Procedures: HIV.STD.Viral Hepatitis Prevention Coordinator
- HIV.STD.Viral Hepatitis Case Reporting: HIV.STD.Viral Hepatitis Surveillance Coordinator
- Ordering of Supplies and Educational Materials: Administrative Assistant

Program Goals for Counseling, Testing and Referral Sites

The HIV and Viral Hepatitis Programs of the North Dakota Department of Health (NDDoH) and the Division of Disease Control aim to reduce the spread of HIV and viral hepatitis, to reduce illness and death and to promote the health and well-being of people with or at risk for these diseases. The goal is to offer HIV and Hepatitis C testing at Counseling, Testing and Referral (CTR) sites to increase accessibility to healthcare services for populations at risk. CTR sites aim to inform clients' knowledge of their HIV and HCV status, counsel and support risk reduction and secure needed referrals (i.e. medical, social, prevention and partner services).

The program is committed to upholding the vision of the National HIV/AIDS strategy, which states:

“The United States will become a place where new HIV infections are rare and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination”

The program also focuses on completing activities of the Viral Hepatitis HHS Action Plan for the Prevention, Care and Treatment of Viral Hepatitis. Increasing the percent of persons who are aware of their hepatitis C virus (HCV) infection is one goal of the action plan that is accomplished at CTR sites through testing of at-risk individuals.

The following are core elements that are essential to all CTR sites:

1. Ensure that CTR is a voluntary service that can only be delivered after informed consent is obtained.
2. Provide information and education to the client about HIV and HCV.
3. Provide client-focused HIV/HCV prevention counseling.
4. Establish clear and easy guidelines and sobriety standards to help counselors determine when clients are not competent to provide consent.
5. Use an HIV and HCV testing technology approved by the Food and Drug Administration (FDA). Testing technology available to sites will be determined by the NDDoH.
6. Deliver test results in a manner that is supportive and understandable to the client.
7. Assess referrals in support of risk reduction or medical care, provide appropriate referrals and help link clients with referral services. A system must be in place for emergency medical or mental health referrals, if needed.
8. Track referrals made and completed.

In addition to the required activities associated with the core elements, CTR sites are recommended to provide comprehensive services, which could include Sexually Transmitted Disease (STD) testing, Human Papilloma Virus (HPV) vaccination and viral hepatitis vaccination at every opportunity. In addition to providing services to incoming clientele, CTR sites, in partnership with the NDDoH and the Community Planning Group (CPG), may offer

outreach services in the community such as rapid testing at health fairs, community events or stand-alone testing events targeting high risk individuals.

Table 1 below summarizes the required and recommended activities performed at CTR sites. A yearly contract is maintained with CTR sites that allow CTR sites to be reimbursed for testing, counseling, vaccine administration fees and other agreed upon expenses. In order to be reimbursed, the CTR site needs to meet standards outlined in this manual and submit required data and other required documentation.

Table 1 . Required and Recommended CTR Activities

Required Activities	Recommended Activities
Obtaining Consent	Outreach events
HIV/Hepatitis C rapid & confirmatory testing	Community education
Pre- and post-test counseling	STD testing
Risk reduction planning	Hepatitis A & B vaccination
Data submission for all tests performed	HPV vaccination
Resource referrals	Case management
Provide client education	Partner services

Eligibility Screening for Testing

Testing supported at CTR sites by the NDDoH is available to individuals considered to be at risk for HIV and/or hepatitis C. Testing should be prioritized for uninsured or underinsured individuals. Individuals seeking testing need to complete a risk assessment. The data from a risk assessment is required to be submitted to the NDDoH for every test performed. There is not a mandatory risk assessment form that needs to be completed, but the risk assessment does need to collect certain data fields. These data fields are described in the document CTR Sites – Required Data Submission available at www.ndhealth.gov/HIV/CTR/CTR.htm. An example of a risk assessment is also available on this website.

Counselors should use the information from a risk assessment to determine which screenings are recommended for an individual. The risk assessment is also used to develop an individual specific risk reduction plan.

HIV Testing

Testing should be provided for people who are or have had:

- Multiple sex partners: (having one or more sexual partners in the last 6 mos.)
- Had unprotected sex: (vaginal, anal or oral sex without protection barriers)
- Current or past injection drug users
- Partners of injection drug users
- Partners of HIV-infected persons
- Persons diagnosed with tuberculosis (TB), HCV or a sexually transmitted disease (STD)
- Men who have sex with men (MSM)
- Tattoos or body piercings in unsterile environments
- Persons who exchange sex for money or drugs

Patients that are at risk for HIV infection should be screened at least annually. Patients that are considered at high risk for HIV infection may be screened every three to six months. Those at high risk include:

- Sex Partners of HIV-infected persons
- Injection drug users and their sex partners
- Persons who exchange sex for money or drugs
- MSM or heterosexual persons who have had, or whose sex partners have had more than one sex partner since their most recent HIV test

HCV Testing

Those that have current risk behaviors should be screened at least annually. People at risk include those who:

- Currently inject drugs or have shared needles, syringes, straws and other equipment
- Injected drugs in the past, even if it was once or many years ago
- Have had tattoos or body piercings in unsterile environments
- Have received blood clotting factors before 1987
- Have HIV or AIDS

- Have had sex with an HIV-infected individual
- Have undiagnosed liver problems
- Have received donated blood or organs before 1992
- Are on long term hemodialysis
- Have had sex with men who have sex with men (MSM)

Rates of HIV infection, viral hepatitis, STDs and TB are substantially higher among persons who use drugs illicitly than among person who do not use drugs. The term "illicit use of drugs" encompasses all levels of use, abuse, and dependence because each level is associated with behaviors that increase the risk for contracting or transmitting infectious diseases. Persons who use drugs illicitly are defined as those who use prescription drugs without prescriptions (e.g., oxycodone), or those who use illicit drugs such as opiates (e.g., heroin), stimulants (e.g., crack cocaine, and methamphetamine), or other so-called "club drugs" (e.g., ketamine and ecstasy). Marijuana use and nonmedical use of prescription drugs also are associated with risk for contracting or transmitting infectious diseases. Persons who inject drugs are at increased risk for HCV infection because of sharing needles and drug-preparation equipment (e.g., water, cotton and a cooker), persons who use illicit drugs, but do not admit to injection drug use, may still be considered for HCV testing due to the possibility that illicit non-injection drug users may be engaging in risky additional risky behaviors. This information was offered from guidance that can be found at www.CDC.gov. Integrated Prevention Services for HIV Infection, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis for Persons Who Use Drugs Illicitly: Summary Guidance from CDC and the U.S. Department of Health and Human Services; 61 (No. RR-05): 1-40).

Several studies have revealed that the rate of sexual transmission of hepatitis C increases with the number of sex partners among heterosexual persons and MSM especially if those partners are co-infected with HIV. In HIV infected men, the hepatitis C virus can be detected in semen and spread through unprotected sex. Other risk factors of hepatitis C; multiple sex partners, rough sex, having sex with an HCV-infected partner or having received a tattoo, piercing or other body art in a non-sterile environment may be tested upon request or at the counselor's discretion. (CDC. Sexually Transmitted Diseases Treatment Guidelines, 2010. MMWR 2010; 59 (No. RR-12): 85-87.)

The CDC recommends that everyone born during 1945 through 1965, also known as "baby boomers", get a one-time test for hepatitis C regardless of known risk factor. People born during 1945 through 1965 are 5 times more likely than other adults to be infected. At CTR sites, the focus is at risk testing and thus **baby boomers are not included** in this program unless they have another specified risk for HCV.

Testing Services Not Provided

Individuals that are ineligible from receiving CTR testing include those who are seeking testing for employee screening, prenatal screening, insurance purchase agreements, travel related, sports team screening or occupational exposure incidents.

A screening reference guide is available at www.ndhealth.gov/HIV/CTR/CTR.htm.

Counseling at CTR Sites

HIV and HCV prevention counseling is a client-centered exchange designed to support individuals in making behavior changes that will reduce their risk of acquiring or transmitting HIV and/or HCV. At CTR sites, all individuals seeking HIV or HCV testing should be provided counseling. Client-focused counseling techniques should be used to help clients determine their readiness for testing and to provide support systems to access while waiting for and after receiving their test results. Client-focused counseling also assesses the client's ability to cope with a positive test result. At the conclusion of the counseling session, a risk reduction plan should be developed with a client and/or appropriate referrals are made based on results and risks.

There are four goals for every counseling session. These include 1) risk assessment, 2) educate client 3) risk reduction planning and 4) result disclosure. The session is typically described in terms of pre-test and post-test counseling. A summary of activities in the pre and post-test counseling session is provided in Table 2.

Table 2. Pre and Post Test Counseling Activities

Pre-Test Counseling	During Waiting Period or Post-Test Counseling
Welcome client and discuss what is going to happen in the session.	Ensure client is ready to receive results. Provide results if client is ready.
Establish rapport.	Describe test and results and clear indicate what those results mean.
Educate client on HIV and hepatitis C.	Awareness of risk. Review risk reduction plan and highlight goals for behavior change.
Assess client's risk and readiness for testing	Provide referrals as necessary.
Provide information on HIV and HCV testing. Include STD testing if appropriate.	Provide recommendations for continual testing if client's continues to have risky behaviors.
Prepare client to receive result.	Establish the overall knowledge of the disease.
Engage client in risk reduction counseling.	Educating about prevention.

Pre-Test Counseling

The pre-test counseling sessions focus on welcoming the client, establishing rapport, providing education about HIV and HCV, risk assessment and engaging the client in risk reduction counseling. Education provided to the client should at least include the type of testing available, risks and benefits of testing, how to prevent and transmit HIV and hepatitis C, window period for testing and where to obtain more information or other healthcare services.

Post-Test Counseling

The post-test counseling can occur the same day as the pre-test counseling if a rapid test is performed or at a later date if a conventional test is performed. A post-test counseling session includes providing test results and an explanation of those results. Review HIV and HCV educational material and develop a client specific risk reduction plan and provide appropriate referral services.

Counseling Negative Individuals

Provide test result in a way that is sensitive and appropriate to the client's needs and level of comprehension. Help the client understand the meaning of the test result. Reemphasize staying negative by helping the client understand how to prevent HIV and/or hepatitis C infection and educate client on screening recommendations, i.e .annually or every more frequent screening.

Counseling Newly Identified HIV and/or HCV Confirmed Positive Individuals

Individuals with positive HIV or hepatitis C confirmatory tests, post-test counseling should ideally be offered face-to-face in a confidential setting.

Post-test counseling for positive individuals should include a discussion of:

- The test results and the reliability and significance of the results;
- Partner services for positive HIV cases;
- Facts about HIV or hepatitis C transmission, emphasizing how to protect close contacts;
- Referrals for medical evaluation, care and treatment including healthcare insurance enrollment and information and referrals for support services, including social and emotional support and substance abuse treatment programs, mental health services or other related programs

At the conclusion of the post-test counseling session, providing information to the client that they can take home is very important. Resource packets are available from the NDDoH for individuals testing positive for HIV or hepatitis C. These resource packets include brochures, fact sheets and information on referral services available. These resource packets can be ordered on the supplies order form.

Additional Information

Providers should develop and maintain strong working relationships with other providers and agencies that might be able to provide needed services. Providers who offer HIV/HCV prevention counseling and testing but not a full range of medical and psychosocial support services should develop arrangements with other providers who can offer needed services. When referral resources are not available locally, providers should identify appropriate resources and link clients with them. Coordination and collaboration promotes a shared understanding of the specific medical and psychosocial needs of clients requiring services, current resources available to address these needs, and gaps in resources.

Supplemental materials for counseling sessions are available www.ndhealth.gov/HIV/CTR/CTR.htm. These materials include a detailed counseling session description, counseling role playing exercise and counseling session summary sheet.

Test Methods Offered at CTR Sites

All tests performed at CTR sites are required to be approved by the FDA. Both rapid and conventional HIV and hepatitis C testing should be available at all CTR sites. Rapid tests are provided to CTR sites free of charge from the NDDoH. Conventional testing, i.e. blood samples are collected at CTR sites and tests are performed at the NDDoH Division of Laboratory Services.

Rapid Testing

Prior to CTR sites initiating rapid testing at their facility, the CTR site needs to obtain a CLIA certificate as the rapid tests are CLIA waived by the FDA and North Dakota Board of Clinical Laboratory Practice. Ensuring compliance with CLIA standards is the responsibility of the CTR site. Ensure all testers are aware of requirements and training necessary prior to testing individuals for HIV and hepatitis C. Refer to the section **Staff Development and Training Policy** in this manual for these requirements.

The rapid HIV test provided to CTR sites is the Clearview® Complete HIV 1 / 2 rapid test manufactured by Alere. This test is to be used on individuals older than 12 years of age. The test is performed with a fingerstick whole blood sample and the result is available in 15 to 20 minutes.

The rapid HCV test provided to CTR sites is the Oraquick® rapid hepatitis C antibody test manufactured by OraSure. This test is to be used on individuals greater than 14 years and cannot be used on pregnant women. The test is performed with a fingerstick sample and the result is available in 20 to 40 minutes.

Confirmatory Testing

All positive rapid tests must be confirmed with a conventional test. Conventional testing is performed at the NDDoH Division of Laboratory Services which is also a confirmatory methodology. When submitting specimens for confirmatory testing, ensure that correct procedures are followed. NDDoH Division of Laboratory Services provides specimen collection procedures and requires submission of completed laboratory request form with each specimen. A courier service may be available in your area to utilize for free shipping of samples.

The type of HIV confirmatory test performed is a fourth generation HIV-1/2 antigen/antibody combination immunoassay. A testing algorithm is available at www.ndhealth.gov/HIV/CTR/CTR.htm.

The hepatitis C confirmatory test available is a confirmatory antibody test as well as a qualitative RNA viral load test. All specimens that have a positive hepatitis C antibody test will be automatically reflexed to the HCV RNA viral load test. When submitting samples for hepatitis C testing, there are temperature requirements for the performance of the HCV RNA testing. Whole blood or serum stored at ambient temperatures must be to the laboratory within 24 hours of collection and specimens that are refrigerated must be to the laboratory within 48 hours. If the time from collection to arrival at the laboratory will be greater than 48 hours, the sample needs to

be frozen at $\geq -20^{\circ}\text{C}$. Algorithms hepatitis C test interpretations are available at www.ndhealth.gov/HIV/CTR/CTR.htm.

Additional questions on specimen collection and submission can be directed to the Division of Laboratory Services at 701.328.6272.

If CTR sites do not offer confirmatory testing, these sites are required to have a written document that details their plan for ensuring that these clients get the confirmatory testing that they need. Sites are encouraged to develop relationships with other CTR sites in their area to offer referrals for blood draws.

Reporting & Documentation

All results need to be reported in MAVEN (additional information in section Required Data Submission). Results should be documented within a patient's chart either via a paper form or electronically. All rapid tests that are invalid need to be reported to the Division of Disease Control. The invalid rapid test form along with an example of a result documentation form is available at: www.ndhealth.gov/HIV/CTR/CTR.htm. Invalid tests should be reported within seven days of specimen collection.

All rapid and confirmatory positive results must be reported to the NDDoH within one business day. Positive results may be reported by calling the Division of Disease Control (701.328.2378), submitting a North Dakota Morbidity Report Card or by using the online report card available at www.ndhealth.gov/disease/reportcard/. Submitting a positive PEMS form is not considered reporting a positive test result.

Control Logs

For all rapid tests, controls are required to be performed for quality assurance. HIV Clearview® Complete and HCV OraQuick® rapid tests require controls to be performed for the following circumstances:

- 1) Each new operator prior to performing tests on patient specimens
- 2) When opening a new test kit lot
- 3) Whenever a new shipment of test kits is received
- 4) If the temperature of the test storage area falls outside:
 - a. HIV Clearview®: 8° to 30°C (46° to 86°F)
 - b. HCV OraQuick®: 2° to 30°C (36° to 86°F)
- 5) If the temperature of the testing area falls outside:
 - a. HIV Clearview®: 18° to 30°C (64° to 86°F)
 - b. HCV OraQuick®: 15° to 37°C (59° to 99°F)
- 6) At periodic intervals as indicated by the user facility. The NDDoH recommends this control testing to be performed every six months for HIV and HCV rapid tests.

When performing controls for a new shipment of test kits, the control logs should be submitted within seven days of shipment receipt. When controls are performed for any other reason, the control log should be submitted monthly.

HIV controls can be ordered on the supplies order form any time when they are needed. For hepatitis C rapid tests, controls are only going to be supplied to CTR sites twice a year. HCV controls are performed on new shipments and lot numbers at the Division of Disease Control. The NDDoH prefers that hepatitis C test kits are not mailed to CTR sites, but instead are hand delivered to ensure the temperature of test kits does not fall outside the appropriate storage window. While hepatitis C controls have an expiration date on the product, they expire two months after first use regardless of expiration date. However, expired controls can be used for new operators.

Temperature Logs

Controls are required to be stored at refrigerator temperatures. HIV and hepatitis C controls should be stored at temperatures of 2° to 8°C (36° to 46°F). If controls are stored in a refrigerator in which the temperatures for that refrigerator are submitted as part of the NDDoH Immunization program, no daily temperatures need to be submitted to the HIV/hepatitis program. If you are using a refrigerator that is not a part of the Immunization Program, daily temperatures need to be recorded to ensure the temperature is within the proper range. The temperature log is then submitted at the end of every month. If temperatures fall outside of the acceptable range for the storage of controls, contact the HIV prevention coordinator.

Additional Information

A supplemental guide is available at www.ndhealth.gov/HIV/CTR/CTR.htm detailing the HIV and hepatitis testing procedures and result interpretation.

Required Data Submission

The North Dakota Department of Health requires certain data elements to be submitted for every HIV and hepatitis C rapid and confirmatory test that is performed. Also, data is required to be submitted for every hepatitis vaccine administered at CTR sites as part of this program. The data submission form includes client demographics, risk factors and testing information and is typically referred to as the PEMS form. These forms are submitted electronically at the following website <https://apps.nd.gov/maven/login.do>. The system in which the data is entered electronically is referred to as MAVEN.

To enter data into MAVEN, users need a username and password. All CTR sites have assigned IDs for both their parent agency and satellite clinics. All individuals performing the rapid tests are considered workers and have assigned IDs as well. New employees or facilities must contact the HIV.STD.Viral Hepatitis prevention coordinator to obtain IDs before performing tests or entering data.

Data submission is due by the 15th of the month for previous month's tests. For example, January data submission is due by February 15. Monthly submissions of PEMS forms will be compared to the number indicated on the reimbursement request. When requesting reimbursement for rapid tests, the number of rapid tests a CTR site requested for reimbursement must match the number of PEMS form submitted for that month. CTR sites will not be reimbursed for rapid tests performed in which there is not a corresponding PEMS form submitted.

Required Data Elements and MAVEN Guide is a user's guide to entering data in MAVEN as well as information on required data elements and is available at www.ndhealth.gov/HIV/CTR/CTR.htm. A print version of the PEMS form is also available on this website.

Policies and Statutes for HIV and HCV Testing

Consent

HIV and HCV testing must be voluntary and undertaken only with the patient's knowledge. Patients must be specifically informed that HIV and HCV testing may be part of their care and have the opportunity to decline testing. Before making this decision, patients should be provided basic information about HIV and HCV and the meaning of positive and negative test results and should have the opportunity to ask questions.

Consent for HIV and HCV testing can be incorporated into general consent for medical care; a separate consent form specific to HIV or hepatitis C is not needed. If a facility does not have a consent form, an example form is available at www.ndhealth.gov/HIV/CTR/CTR.htm. Consent can be given orally or written as long as it is documented in the client's medical record.

N.D.C.C. 14-10-17 states that minors 14 years of age or older may contract for and receive examination, care, or treatment for sexually transmitted diseases such as hepatitis C and HIV, without permission, authority, or consent of a parent or guardian.

Mandatory HIV and HCV Testing

Consent for HIV testing is not required from individuals who are mandated by law to submit to HIV testing. N.D.C.C. 23-07-07.5 states that the following individuals must be examined or tested for the presence of antibodies or antigens of HIV.

1. Every individual convicted of a crime who is imprisoned for fifteen days or more in a grade one or grade two jail, a regional correctional facility, or the state penitentiary;
2. Every individual, whether imprisoned or not, who is convicted of a sexual offense under chapter 12.1-20, except for those convicted of violating sections 12.1-20-12.1-20-13;
3. Every individual, whether imprisoned or not, who is convicted of an offense involving the use of a controlled substance, as defined in chapter 19-03.1, and the offense involved the use of paraphernalia, including any type of syringe or hypodermic needle, that creates an epidemiologically demonstrated risk of transmission of HIV and HCV.

Disclosure of HIV & Viral Hepatitis Status of an Inmate

It is the duty of the counselor to disclose the HIV, hepatitis B (HBV) or hepatitis C (HCV) status of an inmate to medical personnel providing direct care to the individual, the administrator of the correctional facility or as otherwise authorized by law. There should not be any disclosure beyond that, and to the extent there is, disclosure should only be made based on "legitimate penological purposes," or as stated in the HIPAA privacy rule. Within the jail, further disclosure is up to the policies of the administrator and should be on a strictly "need to know basis."

Except as otherwise provided by N.D.C.C. 23-07.5, the results of a test for the presence of an antibody to the human immunodeficiency virus may be disclosed only as follows:

To a correctional institution having lawful custody of an inmate, if the correctional institution represents that such protected health information is necessary for: (a) the provision of health care to the individual; (b) the health and safety of such individual or other inmates; or (c) the health and safety of the officers or employees of or others at the correctional institution. 45 CFR 164.512(k) (5).

Record Maintenance, Location and Retention Policy

The following record retention and maintenance guideline must be followed. In agencies where existing policies are more restrictive, local policies may be followed in lieu of these.

RECORD MAINTENANCE

- N.D.C.C. 23-07.5-04 states that the health care provider that obtains a specimen of body fluids for the purpose of testing for HIV and HCV shall:
 1. Obtain from the subject: the subject's parent, legal guardian, or custodian if the subject is a minor; or the subject's legal guardian if the subject is incapacitated, informed consent for testing or disclosure, unless testing and procedures for disclosure are otherwise provided by law.
 2. Maintain a record of the consent received under subsection 1.
 3. Maintain a record of the test results obtained.
- CDC Standards for HIV and HCV Counseling, Testing and Referral sites require that client records also include:
 1. Documentation of prevention counseling.
 2. Result notification.
 3. Formulation of risk-reduction plans.
- Each individual testing site must retain these records according to the schedule provided below in the Record Retention Schedule.

LOCATION OF RECORDS

HIV and HCV records and reports will be kept in the patient's medical file, if there is one, to ensure health care providers have access to all relevant data when providing patient care. Separate HIV files shall not be kept. If there is no medical file, records must be kept according to the schedule provided in a manner that ensures confidentiality.

RECORD RETENTION SCHEDULE

1. Consent forms must be kept for five years.
2. Negative serology reports must be kept for five years.
3. Positive serology reports must be kept permanently.
4. Other records (e.g., counseling, risk-reduction plan, etc.) should be retained as is routine for other medical file information.
5. Serology reports for patients who do not return to get results should be kept:
 - Permanently, if positive.
 - One year, if negative.

Confidentiality

N.D.C.C. 23-07-02.2 provides that a report of an individual's HIV seropositivity is strictly confidential information and may not be released even through subpoena, search warrant, or discovery proceedings, or otherwise, except that:

1. Release may be made of medical or epidemiologic information for statistical purposes in a manner such that no individual person can be identified;
2. Release may be made of medical or epidemiologic information to the extent necessary to enforce section 23-07-02.1 and this section and related rules concerning the treatment, control, and investigation of human immunodeficiency virus infection by public health officials.
3. Release may be made of medical or epidemiologic information to medical personnel to the extent necessary to protect the health or life of any individual.

No officer or employee of the state department of health may be examined in any proceedings regarding the existence or content on an individual's report.

Anyone breaching confidentiality is guilty of a class C felony (5 years and/or \$5,000).

Annual Security & Confidentiality Attestation

It is required that all persons with direct access to the MAVEN system follow the *North Dakota HIV/AIDS.STD.Tuberculosis.Viral Hepatitis Security & Confidentiality Policy*.

This policy was developed to comply with the Centers for Disease Control and Prevention (CDC) "Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action." This policy applies to all employees, contractors and visitors with access to protected health information (PHI).

This document will be reviewed and updated as needed and/or annually. All staff will be informed of the changes and the location of the most recent policy.

A link to the most recent policy can be found at www.ndhealth.gov/HIV/CTR/CTR.htm.

An annual attestation to the policy is required by all staff with direct access to the MAVEN system. The document that must be signed and returned to the HIV.STD.TB.Viral Hepatitis Program Manager by January 31st of each year for ongoing users, and prior to new users being assigned MAVEN logins. The annual attestation form can be found at www.ndhealth.gov/HIV/CTR/CTR.htm.

Viral Hepatitis Vaccine

Clients to whom the HCV antibody test is offered should also be screened for history of hepatitis A and hepatitis B vaccination and/or previous documented infection. If the client has no prior history of hepatitis A or B vaccination, vaccination with Twinrix, single antigen hepatitis B or single antigen hepatitis A vaccine can be offered to the client free of charge. All clients receiving vaccine provided at the CTR sites must be entered in the North Dakota Immunization Information System (NDIIS) along with documentation of the appropriate vaccine lot number and other information required by the NDDoH Immunization Program. In addition to documenting doses in NDIIS, the client's assessment or vaccine needs are also required questions to be answered on PEMS form.

Hepatitis vaccines are provided to CTR sites through state funding. Ordering of viral hepatitis vaccine will occur twice a year; typically in January and July, depending on funding availability. The viral hepatitis prevention coordinator will contact each CTR site to determine their need for hepatitis vaccine at the time of ordering. This program will support hepatitis A and hepatitis B single antigen vaccines as well as Twinrix vaccine. CTR sites will be reimbursed for the administrative fee for each dose of vaccine administered. Current reimbursement rates are reflected on the reimbursement form.

CTR sites are responsible for ensuring they are in stock vaccine does not expire. If the vaccine at a CTR site is going to be expiring soon, the CTR site should contact the Viral Hepatitis Prevention Coordinator for assistance in finding a facility that would be able to use the vaccine prior to expiration. CTR sites should contact the Viral Hepatitis Prevention Coordinator at least three months prior to their vaccine expiring to ensure adequate time to arrange for transfer to another facility. Sites that have wasted doses of vaccine and have not contacted the viral hepatitis prevention coordinator three months prior to expiration may not receive vaccine in the future as a CTR site.

Staff Development and Training Policy

New Employee Training Requirements

All counselors must adhere to the training requirements of the NDDoH. The CTR site should inform the HIV.STD.Viral Hepatitis Prevention Coordinator of all staff that are newly hired that may perform any duties associated with the CTR program. The following are requirements for all staff that provide counseling and/or test performance at CTR sites:

1. Watch the online OraQuick® Rapid HCV and the Clearview Complete HIV 1 / 2 Training Videos.
 - OraQuick® Rapid HCV Video:
<https://orc.orasure.com/default.aspx?pageid=1995>.
 - Clearview® Rapid HIV Video:
<http://www.alere.com/ww/en/support/edu/product-demos/clearview/clearview-hiv-complete-html5.html>
2. Read product inserts for HIV and HCV rapid testing devices.
3. For HCV, view Visual reference panel.
4. Trained by a qualified individual on test performance and result interpretation.
Note: Only a new CTR needs to be trained by the NDDoH; otherwise all new employees can trained by a qualified (i.e. previously trained) employee.
5. Read CTR manual.
6. View three disease 101 (HIV, Viral Hepatitis & STD) and one counseling online presentations. Presentations are available at: www.ndhealth.gov/HIV/CTR/CTR.htm.
7. View *Delivering HIV Rapid Test Results From the Field*.

Optional: Participate in role playing exercise. Example available at: www.ndhealth.gov/HIV/CTR/CTR.htm

Continuing Education

Every two years, it is required that all CTR testing staff:

- Refresh and test competency for the use of rapid HIV & HCV testing, according to your facilities CLIA policies.
- Review CTR manual.
- Complete re-certification quiz distributed by the HIV.STD.Viral Hepatitis Prevention Coordinator. This quiz will be distributed by email and needs to be completed within 30 days.

The CTR site is responsible for collecting and maintaining records on all staff. Previous staff records need to be retained for two years after termination date. The CTR site shall let the NDDoH if an employee no longer works for the site or no longer has roles and responsibilities associated with the CTR program.

A staff development and training form is available at www.ndhealth.gov/HIV/CTR/CTR.htm.

HIV Prevention and Viral Hepatitis Biannual Site Visit

Every other year, all CTR sites will have a visit conducted by the HIV.STD.Viral Hepatitis Prevention Coordinator. The goal of these sites visits is to ensure compliance with protocols and policies from the HIV and Hepatitis programs. These site visits will highlight strengthens and areas of improvement for each CTR site. All site visits will be coordinated at least three weeks in advance with the point of contact indicated for facility.

The following is minimum list of items that will be discussed at each site visit:

1. Staff Development and Training
 - Documentation of staff completing training requirements
2. Testing Data and Submission
 - Goals for performance standards and metrics
 - Target population being tested and missed
 - Timeliness and completeness of data submission
3. Quality Control
 - Control Logs
 - Control Storage and Handling
 - Test Kit Storage
4. Testing Protocol
 - Documentation of consent
 - Documentation of test results
 - Reviewing facility policy and procedures
5. Vaccine (If Applicable)
 - Doses in NDIIS
 - Completion of Series
6. Educational materials
 - Availability of brochures, safe sex kits, condoms, etc.
7. Referral services
 - Referrals offered by facility to positive patients and those patients in need of support services

Quality Management and Quality Improvement

The purpose of the CTR quality management program is to develop and apply standards of practice in order for CTR services in North Dakota to be of a uniformly high quality and to provide a visible indication that quality to consumers and funders is good.

The results of these metrics will start a conversation around quality improvement of the CTR program on processes and policies to make service delivery more efficient as well as technical assistance to the CTR provider on improvement opportunities to increase the success of the program.

The following are the goals and performance standards of the North Dakota CTR program:

Goal	Performance Standard	Measure	Data Source	Target
CTR services provide tests to people at risk	Proportions of tests are provided to individuals at high risk or from disproportionately affected populations.	Number of tests among high-risk persons/total number of tests	PEMS data submissions	90% of HIV tests performed are among contracted targeted risk populations
				90% of HCV tests performed are among contracted targeted risk populations
CTR services identify people who are HIV positive and don't know their status	CTR non-healthcare test sites maintain a seropositivity rate consistent with NDDoH standards.	Number of positives / total number of tests	PEMS data submissions; surveillance data	HIV: 0.5% seropositivity rate.
	Counselors give rapid test results to individuals in a timely manner.	Number of rapid test results given within 48 hours/ total number of rapid tests	PEMS data submissions	95% of all test results given within 48 hours.
	All individuals confirmed with HIV or HCV are notified of their test results within 5 days of confirmation.	Number of confirmatory positive test results given within 5 days / total number of confirmatory tests	PEMS data submissions; surveillance data	100% of newly diagnosed HIV and HCV positive cases receive their results within 5 days of receipt of lab result.
Link HIV-positive people to care and services	Individuals newly diagnosed with HIV or HCV are linked to medical care.	Number of confirmatory positive patients who follow-up with medical care within 90 days/ total number of confirmatory positive patients.	PEMS data submissions; surveillance data	At least 90% of people diagnosed with HIV are linked to and attends HIV medical care within 90 days.
	Individuals diagnosed with HIV are linked to partner services.	Number of confirmatory positive HIV patients linked to field epidemiologists for partner services / total number of confirmatory positive patients.	PEMS data submissions; surveillance data	100% of newly diagnosed HIV positive cases are linked to partner services within 2 weeks of diagnosis.

	Individuals diagnosed with HIV are linked to prevention services.	Number of confirmatory positive HIV patients linked to case manager for RW referral/ total number of HIV confirmatory positive patients.	CTR forms; surveillance/ Ryan White data	100% of newly diagnosed HIV positive cases are linked to prevention services within 2 weeks.
CTR Counselors will provide high quality services	CTR forms are complete with required information. (Gender, Birth Date, Race, Result of Tests, Risk Factors)	Number of forms with fully complete data submitted / total number of forms submitted.	CTR forms	95% of CTR forms received have complete information.
	CTR counselors are able to accurately interpret test results.	Number of staff that are trained and proficient in testing methodologies / total number of staff that perform testing.	Training records.	100% of counselors will demonstrate their HIV and HCV testing proficiency.
	CTR counselors have received training related to results delivery and counseling.	Number of staff that are trained and proficient in results delivery and counseling / total number of staff that perform testing.	Training records, bi-annual assessment.	100% of counselors will demonstrate their proficiency HIV and HCV results delivery and counseling.
CTR Sites are compliant with contract requirements	CTR requests for reimbursement are submitted timely via PRS and have the necessary documentation attached.	Number of requests for reimbursement received with appropriate documentation and on time / total number of requests for reimbursement.	PRS data.	80% of all requests for reimbursement will be submitted by the 15 th of the next month and with required documentation.
	CTR sites submit required patient level information (PEMS) within one week of test performance.	Number of PEMS forms submitted within a week of test performance / total number of PEMS forms submitted.	PEMS data.	80% of PEMS forms will be submitted within one week of test performance.
	CTR sites report positive results within 24 hours of positive result.	Number of positive test results reported within 24 hours / total number of positive test results.	PEMS data; surveillance data.	95% of positive tests will be reported with 24 hours of positive result.

Grant Awards & Contracts for CTR Program

Grant opportunities to provide funding to sites to administer the HIV/HCV CTR program will be made available in late fall/early winter each year to participate in the program for the next upcoming calendar year. Contracts will be awarded for the time period January 1-December 31. This program is designed to provide funding to administer HIV and HCV tests to patients who are at risk for infection and are uninsured and underinsured at no cost to them. For patients who are insured and at risk, CTR sites may use the supplies of the CTR program, however the cost of counseling and test administration should be billed to that patients insurance and not billed to the CTR program.

The contract awarded will contain a dollar amount that represents a pooled account of funds for all sites to draw off of. This amount is variable from year to year based on federal and state funding. Once this pool is expended, sites will no longer be able to request reimbursement for tests, however, testing with the CTR program supplies may continue. The HIV.STD.TB.Viral Hepatitis Program Manager will alert sites when and if the funding has expired. Requests for reimbursement will be processed in the order in which they are received.

Grant opportunities related to vaccine administration and the linkage of care services for those diagnosed with HCV will also be made available to CTR sites who are also providers of state supplied HAV and HBV vaccine to persons are at high risk for HCV infection or persons who are HCV infected. Contracts will be awarded along the same timeline of the state biennium. CTR awardees will be notified of the availability of these fund and will have the opportunity to apply for them when they become available.

Reimbursement for Testing, Counseling and Vaccination

The reimbursement form should be completed and submitted on a monthly basis to the North Dakota Department of Health HIV.STD.TB.Viral Hepatitis Program Manager via the Program Reporting System (PRS). The worksheet provided by the CTR program must be included as an attachment to the request for reimbursement in order for it to be processed. This document serves as the monthly progress report for each site. The reports are due 15 days after the end of the month. The final expenditure report ending December 31st must be received by February 15th.

If you do not have any reimbursements for the month, please submit a report for the month in PRS regardless showing a zero amount for request for the month. This ensures that the months of reimbursement stay consistent. Likewise, multiple months of reimbursement requests may be submitted as long as it is indicated in both the PRS system as well as on the reimbursement attachment.

Allowable expenses and reimbursement rates are detailed on the worksheet used to determine your level of reimbursement.

The most current worksheet for reimbursement requests can be found at:
www.ndhealth.gov/HIV/CTR/CTR.htm.

HIV and HCV Testing at Outreach Events

Counseling, testing and referral sites can partner with North Dakota Department of Health Division of Disease Control to coordinate HIV, STD and hepatitis C testing at various locations across North Dakota such as homeless shelters, veterans events, etc. Outreach should target at-risk populations. All outreach events need to be approved by the NDDoH.

Outreach events are an important factor in HIV and STD and hepatitis prevention as it targets individuals who may not access testing and education in typical healthcare settings. In addition, hosting testing events for awareness days such as Hepatitis Testing Day on May 19 or World AIDS Day on December 1 is another way to increase awareness in the community. Additional support can be provided to CTR sites if there is interest in outreach or testing events.

Contact the NDDoH at least 30 days prior to a testing or outreach event. When planning on outreach or testing event special considerations are needed for event advertisement, ensuring confidentiality, specimen collection, result delivery and other logistics concerns. The HIV and hepatitis program can provide assistance in organizing and hosting an event. Depending on the expected size of the event, additional testing supplies may be needed and free STD testing may be available at these events as well.

The North Dakota Department of Health and its partners have seen success in outreach events held throughout the state. An outreach toolkit is available at www.ndhealth.gov/HIV/CTR/CTR.htm. Please contact the NDDoH with any questions regarding outreach testing.

Ordering Prevention and Testing Supplies

All supplies, including condoms, educational materials, rapid tests, controls and other prevention supplies are ordered by completing an order form. This order form (HIV Prevention Supplies and Information Order Form) is available at www.ndhealth.gov/HIV/CTR/CTR.htm. Complete this form in its entirety when ordering supplies. Incomplete information may cause a delay in the order. Some supplies have a limit as to the quantity that may be ordered.

Please allow 1-2 weeks for delivery. Longer delivery times may be imposed when the weather is extremely cold or hot. Many prevention supplies, including HIV and hepatitis C rapid tests cannot be shipped in freezing temperatures.

As a reminder, hepatitis C rapid test kits are not preferably shipped in the mail, but instead preferred to be hand delivered. Delivery arrangements will be made if NDDoH is traveling to the location of a CTR or CTR site employees can pick up tests at the Disease Control office.

Mail or fax orders to HIV.Viral Hepatitis Administrative Assistant at 701.328.2499. If there are any questions regarding ordering, please call 701.328.2376.